# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

| IN RE PHARMACEUTICAL INDUSTRY<br>AVERAGE WHOLESALE PRICE<br>LITIGATION | ) ) ) MDL No. 1456 ) Civil Action: 01-CV-12257-PBS _) |
|--|---|
| THIS DOCUMENT RELATES TO:<br>ALL CLASS ACTIONS                         | ) Hon. Patti B. Saris ) )                             |

# AMGEN INC.'S ANSWER TO PLAINTIFFS' FOURTH AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT

Defendant Amgen Inc. ("Amgen") hereby responds to the Fourth Amended Master Consolidated Class Action Complaint (the "FAMCC") in corresponding numbered paragraphs as follows:

#### Preface

To the extent that the FAMCC makes allegations that refer to the knowledge, conduct, or actions of others, Amgen is generally without knowledge or information sufficient to form a belief as to the truth or falsity of those allegations and, on that basis, denies those allegations.

The FAMCC improperly mixes factual allegations with vague and conclusory allegations, making it impossible for Amgen to prepare a meaningful response to such allegations. The FAMCC also includes undefined terms that are susceptible to different meanings. In addition, the FAMCC contains purported quotations from a number of different sources, many of which are unidentified. In answering allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or

entity quoted shall not constitute an admission that the substantive content of the quote is or is not true or that the material is relevant or admissible in this action.

Amgen denies each and every factual allegation contained in the FAMCC, except as specifically admitted herein. Amgen specifically denies any allegations contained in headings, footnotes, the Table of Contents, or unnumbered paragraphs in the FAMCC.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

# I. INTRODUCTION

- Amgen admits that Plaintiffs seek to bring this action as alleged in
   Paragraph 1 of the FAMCC. Amgen denies that Plaintiffs are entitled to maintain this action in the manner alleged.
- 2. To the extent the allegations in Paragraph 2 of the FAMCC allege a conspiracy between Amgen and various publishing entities, no response is required because these allegations, which formed the basis of Count I of the FAMCC, were dismissed with prejudice by the Court's Order dated February 24, 2004. Amgen further denies the remaining allegations in Paragraph 2 of the FAMCC.
- 3. To the extent that the allegations in Paragraph 3 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.
- 4. Amgen admits that Congress has mandated that Medicare Part B reimbursements be based, in part, in certain circumstances, upon AWP, and further admits that Medicare Part B medicines are generally, but not always, administered in a healthcare provider's office. To the extent that the remaining allegations in Paragraph 4 of the FAMCC are directed at

defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.

- 5. Amgen admits that AWP is used by certain entities for reimbursement purposes. To the extent that the remaining allegations in Paragraph 5 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied. Amgen specifically denies the existence of, and its participation in, any "AWP scheme."
- 6. Amgen admits that Plaintiffs purport to bring this action as alleged in Paragraph 6 of the FAMCC, but Amgen denies that Plaintiffs are entitled to maintain this action in the manner alleged. To the extent that the remaining allegations in Paragraph 6 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.
- 7. To the extent that the allegations in Paragraph 7 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.
- 8. Amgen admits that Plaintiffs have filed attachments to the FAMCC. To the extent the allegations in Paragraph 8 of the FAMCC are deemed to include allegations against Amgen, they are denied.

# II. JURISDICTION AND VENUE

9. Amgen admits that this Court has subject matter jurisdiction, subject to the political question and other defenses raised below. Upon information and belief, Amgen admits that this Court has diversity jurisdiction.

- 10. Admitted.
- 11. Amgen admits that venue is proper in this jurisdiction for purposes of pretrial proceedings as alleged by Plaintiffs, but denies that venue is proper in this jurisdiction for trial or other non-MDL purposes. To the extent that the remaining allegations in Paragraph 11 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied. Amgen specifically denies the existence of, and its participation in, any alleged "fraudulent marketing scheme."

#### 12. Admitted.

# III. PARTIES

- 13. Amgen is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13 of the FAMCC and, therefore, denies those allegations.
- 14-61. Amgen admits that the Plaintiffs identified in Paragraphs 16 through 61 purport to bring this action as alleged, but Amgen denies that these Plaintiffs have standing to bring the alleged action. Amgen is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 14 through 61 of the FAMCC and, therefore, denies those allegations. Further, Amgen denies that the individuals and entities named in the referenced allegations are appropriate class representatives.
- 62. Amgen is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 62 of the FAMCC and, therefore, denies those allegations.

- 63-67. Amgen admits that Plaintiffs VPIRG, WCA, StateWide, CANY and CCJ purport to bring this action as alleged in Paragraphs 63-67 of the FAMCC, but Amgen denies that these Plaintiffs have standing to bring the alleged action. Amgen is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraphs 63-67 of the FAMCC and, therefore, denies those allegations. To the extent that Plaintiffs are raising claims under the Clayton Act, those counts have been voluntarily dismissed and, therefore, do not require a response.
- 68-69. To the extent that the allegations in Paragraphs 68 and 69 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.
- 70-72. The allegations in Paragraphs 70 through 72 of the FAMCC are directed at defendants other than Amgen. Thus, no response is required. To the extent that the allegations in Paragraphs 70 through 72 of the FAMCC are deemed to include allegations against Amgen, they are denied.
- 73-74. Amgen admits it is a Delaware corporation with its principal place of business located at One Amgen Drive, Thousand Oaks, California. Amgen further admits that it is in the business of researching, developing, manufacturing, and marketing biologics and other pharmaceutical products, including products that are reimbursed under Medicare Part B. Amgen also admits that it manufactures Epogen and Neupogen.
- 75-144. The allegations in Paragraphs 75 through 144 of the FAMCC are directed at defendants other than Amgen. Thus, no response is required. To the extent that the allegations in Paragraphs 75 through 144 of the FAMCC are deemed to include allegations against Amgen, they are denied.

# IV. GENERAL ALLEGATIONS

- 145. Paragraph 145 simply characterizes the FAMCC, accordingly no response is required. To the extent a response is required of Amgen, Amgen denies the allegations contained in Paragraph 145 of the FAMCC.
- 146. Amgen is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 146 of the FAMCC and, therefore, denies those allegations. Upon information and belief, Amgen admits the allegations in the second sentence of Paragraph 146 of the FAMCC.
- 147. Amgen admits that Congress mandated that Medicare Part B reimbursement be based, in part, in certain circumstances, on AWP. To the extent that the remaining allegations in Paragraph 147 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.
- 148. Amgen admits that independently produced pricing publications periodically publish AWPs for prescription medicines sold in the United States. Amgen is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 148 of the FAMCC and, therefore, denies those allegations.
- 149. Amgen admits that the 1999 edition of the *Red Book* and the June 1966 Dow Jones News article cited in Paragraph 149 exist. To the extent that the remaining allegations in Paragraph 149 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.
- 150-154. To the extent that the allegations in Paragraphs 150 through 154 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.

- 155-157. Paragraphs 155 through 157 of the FAMCC state legal conclusions to which no response is required. To the extent a response is required of Amgen, Amgen admits that the regulations and statutes cited in Paragraphs 155 through 157 of the FAMCC exist, but denies that Plaintiffs have accurately characterized any conclusions that may be drawn from those regulations and statutes. Amgen denies the remaining allegations in Paragraphs 155 through 157 of the FAMCC.
- 158. Amgen admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth, in part, at 42 CFR § 405.517. To the extent that Plaintiffs purport to summarize or characterize 42 CFR § 405.517, Paragraph 158 of the FAMCC states a legal conclusion to which no response is required. To the extent a response is required of Amgen, Amgen denies the allegations in Paragraph 158 of the FAMCC.
- 159. Paragraph 159 of the FAMCC states legal conclusions to which no response is required. To the extent a response is deemed required, Amgen admits that federal statutes and regulations set forth the payment methodology for drugs under Medicare Part B. Amgen is without knowledge or information sufficient to form a belief as to the accuracy of the unattributed quotations in Paragraph 159 of the FAMCC. Amgen denies the remaining allegations in Paragraph 159 of the FAMCC.
- 160. Amgen admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth, in part, at 42 CFR § 405.517. To the extent that Plaintiffs purport to summarize or characterize 42 C.F.R. § 405.517, Paragraph 160 of the FAMCC states a legal conclusion to which no response is required. To the extent a response is required of Amgen, Amgen denies the allegations in Paragraph 160 of the FAMCC.

- 161-162. Paragraphs 161-162 of the FAMCC state legal conclusions to which no response is required. To the extent a response is required of Amgen, Amgen admits that Program Memorandum AB-99-63 does exist, but denies that Plaintiffs have accurately characterized any conclusion that may be drawn from it. Amgen denies the remaining allegations in Paragraphs 161-162 of the FAMCC.
- 163. Paragraph 163 of the FAMCC states legal conclusions to which no response is required. Amgen admits that federal law governs the manner in which Medicare Part B reimburses medical providers for certain drugs. Amgen is without knowledge or information sufficient to form a belief as to whether the summary of those laws set forth in Paragraph 163 of the FAMCC is accurate in all instances. Accordingly, to the extent a response is required, Amgen denies the allegations in Paragraph 163 of the FAMCC.
- 164. Upon information and belief, Amgen admits the allegations in Paragraph 164 of the FAMCC.
- AWPs are calculated, nor any other statutory or regulatory definitions or descriptions of AWPs.

  Amgen admits that it reports certain pricing information for its products to independently produced pricing publications. Amgen denies the remaining allegations in Paragraph 165 of the FAMCC.
- 166-167. Amgen admits that the April 2003 OIG Guidance cited in Paragraphs 166 through 167 of the FAMCC exists. Amgen denies that Plaintiffs have accurately characterized any alleged OIG finding, opinion, statement, or conclusion, or that such are applicable to Amgen. Amgen denies the remaining allegations in Paragraphs 166 through 167 of the FAMCC.

- 168. Upon information and belief, Amgen admits certain federal and state agencies have investigated marketing and pricing practices of various manufacturers with respect to certain Medicare and Medicaid reimbursable products. Amgen denies the remaining allegations in Paragraph 168 of the FAMCC.
- 169-170. Amgen admits that the September 28, 2000 letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 169 through 170 of the FAMCC exists. Amgen denies that Plaintiffs have accurately characterized the findings, opinions, statements, or conclusions of Congressman Stark, or that such are applicable to Amgen. Amgen denies the remaining allegations in Paragraphs 169 through 170 of the FAMCC.
- 171. Amgen is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 171 of the FAMCC and, therefore, denies those allegations.
- 172-196. To the extent the allegations in Paragraphs 172 through 196 of the FAMCC refer to the knowledge, conduct, or actions of persons or entities other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Amgen denies the remaining allegations in Paragraphs 172 through 196 of the FAMCC.
- 197. The first two sentences of Paragraph 197 of the FAMCC state legal conclusions to which no response is required. To the extent a response is required of Amgen, Amgen admits that federal statutes and regulations set forth the payment methodology for drugs under Medicare Part B. To the extent that the allegations in Paragraph 197 of the FAMCC are

directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.

198. Amgen is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 198 of the FAMCC and, therefore, denies those allegations.

199-204. To the extent that the allegations in Paragraphs of 199 through 204 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.

205. To the extent that the allegations in Paragraph 205 of the FAMCC are directed at defendants other than Amgen, no response is required. Amgen admits that the 2003 CMS document cited in Paragraph 205 of the FAMCC exists. Amgen denies that Plaintiffs have accurately characterized any alleged CMS finding, opinion, statement or conclusion. Amgen admits that it sells its pharmaceuticals in a competitive market and, as such, takes steps to keep certain information relating to its pharmaceuticals confidential. Amgen denies the remaining allegations in Paragraph 205 of the FAMCC.

206-210. To the extent that the allegations in Paragraphs 206 through 210 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.

211-212. The allegations in Paragraphs 211 through 212 of the FAMCC state legal conclusions to which no response is required. To the extent that the remaining allegations in Paragraphs 211 and 212 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.

# V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

213. To the extent that the allegations in Paragraph 213 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.

214-229. The allegations in Paragraphs 214 through 229 of the FAMCC are directed at defendants other than Amgen. Therefore, no response is required. To the extent that the allegations in Paragraphs 214 through 229 of the FAMCC are deemed to include allegations against Amgen, they are denied.

230. Amgen admits only that the FAMCC purports to seek relief in connection with the various Amgen products identified in Paragraph 230. It denies the remaining allegations in Paragraph 230.

The following paragraphs were incorrectly numbered in the FAMCC. Amgen will respond to the paragraphs as the Plaintiffs have numbered them.

224A. Amgen admits it introduced Epogen in 1989 and that Epogen is indicated for the treatment of anemia in patients with chronic renal failure on dialysis. Amgen admits that Aranesp is an erythropoietic protein with a longer half-life than epoetin alfa, which leads to greater biological activity. Amgen admits Aranesp was approved in September 2001 for the treatment of anemia in patients with chronic renal failure and that in July 2002, the FDA approved Aranesp for use in the treatment of chemotherapy-induced anemia in patients with nonmyeliod malignancies. Aranesp's U.S. sales for 2002 were \$284.7 million.

224B. Admitted.

231. Denied.

- 225A. To the extent that the allegations in Paragraph 225A of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent Paragraph 225A references Amgen's website, the content of the website speaks for itself. Amgen denies the remaining factual allegations that pertain to it.
- 225B. To the extent that the allegations in Paragraph 225B of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied. Amgen further states that Ortho Biotech's website speaks for itself.
  - 232. Denied.
- 226A. Amgen admits only that Leukine is considered a competitor of Neupogen.

  Amgen denies the remaining allegations in Paragraph 226A of the FAMCC.
- 226B. To the extent Paragraph 226B cites to Amgen's website, the website speaks for itself.
  - 233. Denied.
- 227A. The excerpt quoted in Paragraph 227A of the FAMCC speaks for itself.

  Amgen denies the remaining factual allegations set forth in this paragraph.
  - 227B. Denied.
- 234. The unattributed comment quoted in Paragraph 234 of the FAMCC speaks for itself. Amgen denies the remaining factual allegations set forth in this paragraph.
  - 228A. Denied.
- 228B. Amgen admits that it has established a website to help providers having questions concerning, among other things, reimbursement for Amgen products, and has also established a Reimbursement Hotline for similar purposes.

235. The excerpt quoted in Paragraph 235, which purports to be from Amgen's website, speaks for itself.

229A. Denied.

229B. Denied.

236. Denied.

230A. Denied.

230B. Denied.

237. Denied.

231A. Denied.

231B. To the extent that the allegations in Paragraph 231B of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.

238. Denied.

232A. Amgen admits only that Leukine is considered a competitor of Neupogen. To the extent that the allegations in Paragraph 232A of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.

232B. The excerpt quoted in Paragraph 232B, which purports to be from a Centecor document, speaks for itself. To the extent that the allegations in Paragraph 232B of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.

239. Denied.

233A. Denied.

233B. Denied.

240. Denied.

234A. Denied.

2334B. Denied.

241. The OIG report cited in Paragraph 241 of the FAMCC speaks for itself.

Amgen denies that Plaintiffs have accurately characterized any alleged finding, opinion, statement, or conclusion set forth in that report.

235A. Denied.

242. Denied.

236A. Denied.

243. To the extent that the allegations of Paragraph 243 refer or relate to Amgen's product, Epogen, the allegations are denied. By way of further response, Amgen admits that the GAO report, the terms of which speak for itself, identifies epoetin alfa for non-ESRD use (i.e., Procrit), as accounting for approximately 9.5% of spending for prescription drugs by Medicare.

237A. Denied.

244-501. The allegations in Paragraphs 244 through 501 of the FAMCC are directed at defendants other than Amgen. Therefore, no response is required of Amgen. To the extent that the allegations in Paragraphs 244 through 501 of the FAMCC are deemed to include allegations against Amgen, they are denied.

# VI. DIRECT DAMAGE SUSTAINED BY PLAINTIFFS AND THE MEMBERS OF THE AWP CLASS

502. Amgen is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 502 of the FAMCC and, therefore, denies those allegations.

# VII. CLASS ACTION ALLEGATIONS FOR THE AWP PAYOR SCHEME

503-508. Amgen admits that Plaintiffs purport to bring this action as alleged in Paragraphs 503-508 of the FAMCC, but Amgen denies that Plaintiffs are entitled to maintain this action in the manner alleged. Amgen denies that Plaintiffs or any putative class members have suffered damages as alleged in Paragraph 508 of the FAMCC. Amgen further denies the remaining allegations in Paragraphs 503-508 of the FAMCC.

509-512. The allegations in Paragraphs 509 through 512 of the FAMCC state legal conclusions to which no response is required. Amgen denies, however, that Plaintiffs have pled a proper class or named proper class representatives. Amgen further denies that Plaintiffs or any putative class members have suffered damages or injuries or will suffer damages or injuries as alleged in Paragraph 512 of the FAMCC. Amgen denies the remaining allegations in Paragraphs 509 through 512 of the FAMCC.

#### **COUNT I**

513-541. The Court dismissed Count I in its Order dated February 24, 2004. Accordingly, Amgen does not need to respond to Paragraphs 513 through 541 of the FAMCC. To the extent a response is required, Amgen denies all allegations in Count I of the FAMCC.

#### **COUNT II**

- 542. Amgen realleges and incorporates by reference its responses to Paragraphs 1 through 541 of the FAMCC.
- 543. Amgen admits that Plaintiffs purport to bring this action and to seek relief under Count II of the FAMCC as alleged in Paragraph 543, but Amgen denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against Amgen under Count II. Amgen further denies the remaining allegations in Paragraph 543 of the FAMCC.
- 544. The allegations in Paragraph 544 of the FAMCC state a legal conclusion to which no response is required. Amgen denies, however, that Plaintiffs have pled a proper class.
- 545. To the extent the allegations in Paragraph 545 of the FAMCC and subparts state legal conclusions, no response is required. Amgen is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 545 and subparts and, therefore, denies those allegations.
- 546-550. To the extent allegations in Paragraphs 546 through 550 of the FAMCC state legal conclusions, no response is required. Also, to the extent the allegations in Paragraphs 546 through 550 of the FAMCC refer to the knowledge, conduct or actions of persons or entities other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Amgen further denies that Plaintiffs have accurately characterized any alleged "industry report" finding, opinion, statement, or conclusion. Amgen further denies the remaining allegations in Paragraphs 546 through 550.

"enterprise," "AWP spread scheme," "AWP Scheme," "The Amgen Manufacturer-PBM Enterprise" and/or "Manufacturer-PBM Enterprise" as alleged in Paragraphs 551 through 574 of the FAMCC. To the extent allegations in Paragraphs 551 through 574 of the FAMCC state legal conclusions, no response is required. Also, to the extent the allegations in Paragraphs 551 through 574 of the FAMCC refer to the knowledge, conduct or actions of persons or entities other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Amgen further denies that Plaintiffs have pled a proper class or named proper class representatives. Amgen denies the remaining allegations in Paragraphs 551 through 574 of the FAMCC.

#### **COUNT III**

- 575. Amgen realleges and incorporates by reference its responses to Paragraphs 1 through 574 of the FAMCC. Amgen admits that Plaintiffs purport to bring this action as alleged in Paragraph 575 of the FAMCC, but Amgen denies that Plaintiffs are entitled to maintain this action in the manner alleged or to any relief against Amgen in Count III. Amgen further denies that Plaintiffs have pled a proper class or named proper class representatives.

  Amgen further denies the remaining allegations in Paragraph 575 of the FAMCC.
- 576. The allegations in Paragraph 576 of the FAMCC state legal conclusions to which no response is required. To the extent a response is required, Amgen denies that Plaintiffs have standing to bring this action, and denies that an actual case and controversy exists. To the extent that the allegations in Paragraph 576 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.

577-578. Answering the first sentence of Paragraph 577 of the FAMCC, Amgen refers to and incorporates its response to Paragraph 576 of the FAMCC. Amgen further denies that Plaintiffs have pled a proper class or named proper class representatives. Amgen denies the remaining allegations in Paragraphs 577 through 578 of the FAMCC.

#### **COUNT IV**

- 579. Amgen realleges and incorporates by reference its responses to Paragraphs 1 through 578 of the FAMCC.
- 580. Amgen admits that Plaintiffs purport to bring this action and to seek relief under Count IV of the FAMCC as alleged in Paragraph 580, but Amgen denies that Plaintiffs are entitled maintain this action as alleged or to any relief against Amgen under Count IV. Amgen further denies the remaining allegations in Paragraph 580 of the FAMCC.
- 581. To the extent the allegations in Paragraph 581 and subparts state legal conclusions, no response is required. Moreover, to the extent that the allegations in Paragraph 518 of the FAMCC are directed at defendants other than Amgen, no response is required. Amgen admits that its principal place of business is located in California. Amgen further admits that certain states have enacted consumer protection laws, but Amgen denies that it has violated such laws or that Plaintiffs or any putative class members are entitled to relief under such laws. Amgen further denies the remaining allegations in Paragraph 581 of the FAMCC.
- 582-586. To the extent allegations in Paragraphs 582 through 586 state legal conclusions, no response is required. Also, to the extent that the allegations in Paragraphs 582 through 586 of the FAMCC are directed at defendants other than Amgen, no response is

required. To the extent they are directed at Amgen, they are denied. Amgen further denies that Plaintiffs have pled a proper class or named proper class representatives.

#### COUNT V

- 587. Amgen realleges and incorporates by reference its responses to Paragraphs 1 through 586 of the FAMCC. Amgen admits that Plaintiffs purport to bring this action as alleged in Paragraph 587 of the FAMCC in the event the Court does not apply the laws asserted as applicable in Count IV.
- 588. Amgen admits that the Plaintiffs purport to bring this action as alleged in Paragraph 588 of the FAMCC, but Amgen denies that Plaintiffs are entitled to maintain this action in the manner alleged or to any relief against Amgen in Count V. Amgen further denies that Plaintiffs have pled a proper class or named proper class representatives. Amgen denies the remaining allegations in Paragraph 588 of the FAMCC.
- 589. Amgen admits that Plaintiffs propose the identified individuals as class representatives, but to the extent that the allegations in Paragraph 589 of the FAMCC are directed at Track 1 defendants, no response is required of Amgen. Moreover, Amgen is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 589 of the FAMCC and, therefore, denies those allegations. Amgen further denies that Plaintiffs have pled a proper class or named proper class representatives. Amgen denies the remaining allegations in Paragraph 589 of the FAMCC.
- 590. Amgen admits that Plaintiffs propose the identified individuals as class representatives, but Amgen is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 590 of the FAMCC and, therefore, denies those

allegations. Amgen further denies that Plaintiffs have pled a proper class or named proper class representatives. Amgen denies the remaining allegations in Paragraph 590 of the FAMCC.

- 591. Amgen admits that Plaintiffs seek class certification for these claims, but Amgen denies that Plaintiffs are entitled to maintain this action in the manner alleged or to any relief against Amgen in Count V.
- 592-593. The extent that Paragraphs 592 though 593 of the FAMCC and subparts state legal conclusions, no response is required. To the extent that the allegations in Paragraphs 592 through 593 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.
- 594. To the extent that the allegations relate to the notice provided to entities other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 594 and, therefore, denies those allegations. Amgen denies the remaining allegations in Paragraph 594 of the FAMCC.
- 595. Amgen is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 595 and, therefore, denies those allegations.

#### **COUNT VI**

- 596. Amgen realleges and incorporates by reference its responses to Paragraphs 1 through 595 of the FAMCC. Amgen admits that Plaintiffs purport to bring this action as alleged in Paragraph 596 of the FAMCC in the event the Court does not apply the laws asserted as applicable in Count IV.
- 597-598. Amgen admits that Plaintiffs propose the identified individuals as class representatives, but to the extent that the allegations in Paragraphs 597 and 598 of the

FAMCC are directed at Track 1 defendants, they require no response from Amgen. Amgen admits that the Plaintiffs purport to bring this action as alleged in Paragraph 597 through 598 of the FAMCC, but Amgen denies that Plaintiffs are entitled to maintain this action in the manner alleged or to any relief against Amgen in Count V. Amgen further denies that Plaintiffs have pled a proper class or named proper class representatives. Amgen denies the remaining allegations in Paragraph 597 through 598 of the FAMCC.

- 599. Amgen admits that Plaintiffs seek class certification for this claim, but Amgen denies that Plaintiffs are entitled to maintain this action in the manner alleged or to any relief against Amgen in Count VI.
- 600-601. The extent that Paragraphs 600 though 601 of the FAMCC and subparts state legal conclusions, no response is required. Also, to the extent that the allegations in Paragraphs 600 and 601 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.
- 602. To the extent that the allegations relate to the notice provided to entities other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 602 and, therefore, denies those allegations. Amgen denies the remaining allegations in Paragraph 602 of the FAMCC.
- 603. Amgen is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraph 603 and, therefore, denies those allegations.

## **COUNT VII**

604. Amgen realleges and incorporates by reference its responses to Paragraphs 1 through 603 of the FAMCC. Amgen admits that Plaintiffs purport to bring this action as

alleged in Paragraph 604 of the FAMCC in the event the Court does not apply the laws asserted as applicable in Count IV.

- 605. Amgen admits that Plaintiffs seek class certification for this claim, but Amgen denies that Plaintiffs are entitled to maintain this action in the manner alleged or to any relief against Amgen in Count VII.
- 606. Amgen admits that Plaintiffs propose the identified individuals as class representatives in this paragraph, but to the extent that the allegations in Paragraph 606 of the FAMCC are directed at Track 1 defendants, they require no response from Amgen. Moreover, Amgen is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 606 of the FAMCC and, therefore, denies those allegations. Amgen further denies that Plaintiffs have pled a proper class or named proper class representatives. Amgen denies the remaining allegations in Paragraph 606 of the FAMCC.
- 607-608. Amgen denies that Plaintiffs have pled a proper class or named proper class representatives. Amgen denies the remaining allegations in Paragraphs 607 through 608 of the FAMCC.
- 609. Amgen denies this allegation insofar as it is inconsistent with this Court's rulings.
- 610. Amgen denies that Plaintiffs have pled a proper class or named proper class representatives. Amgen denies the remaining allegations in Paragraph 610 of the FAMCC.
- 611-613. The extent that Paragraphs 611 though 613 of the FAMCC and subparts state legal conclusions, no response is required. Also, to the extent that the allegations in Paragraphs 611 through 613 of the FAMCC are directed at defendants other than Amgen, no response is required. To the extent they are directed at Amgen, they are denied.

#### **COUNT IX**

- 614. Amgen realleges and incorporates by reference its responses to Paragraphs 1 through 613 of the FAMCC.
- 615. Amgen admits that Plaintiff CMHV purports to bring this action as alleged in Paragraph 615 of the FAMCC, but Amgen denies that Plaintiff CMHV is entitled to maintain this action in the manner alleged or that CMHV is a proper class representative. Amgen is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 615 of the FAMCC and, therefore, denies those allegations.
- 616-619. To the extent the allegations in Paragraphs 616 through 619 of the FAMCC and subparts state legal conclusions, no response is required. Also, to the extent the allegations in Paragraphs 616 through 619 of the FAMCC refer to the knowledge, conduct or actions of persons or entities other than Amgen, Amgen is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Amgen denies the remaining allegations in Paragraphs 616 through 619 of the FAMCC and subparts.
- 620-621. The allegations in Paragraphs 620 through 621 of the FAMCC state legal conclusions to which no response is required. To the extent a response is required of Amgen, Amgen denies the allegations in Paragraphs 620 through 621 of the FAMCC.

# UNNUMBERED "WHEREFORE" PARAGRAPH AND REQUEST FOR JURY TRIAL

Amgen denies Plaintiffs are entitled to a judgment or any other relief requested in their Prayer for Relief and "WHEREFORE" paragraph following Paragraph 621 of the FAMCC.

Listed below, Amgen has provided a list of defenses without assuming any burden of proof:

# First Defense

Plaintiffs and the putative class fail to state a claim against Amgen upon which relief may be granted.

#### **Second Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the political question and separation of powers doctrines.

# **Third Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the filed rate doctrine.

# Fourth Defense

Plaintiffs and the putative class have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Amgen as alleged in the FAMCC.

#### Fifth Defense

To the extent Plaintiffs and/or any member of the putative class obtain recovery in any other case predicated on the same factual allegations, that Plaintiff or purported class member is barred from seeking recovery against Amgen based on the FAMCC pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

#### Sixth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitutions of the various States whose laws are or become relevant in the course of this multidistrict litigation.

# **Seventh Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Amgen in judicial, legislative, or administrative proceedings of any kind or at any level of government.

# **Eighth Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, to the extent that Plaintiffs and the putative class members have released, settled, entered into an accord and satisfaction or otherwise compromised their claims.

#### Ninth Defense

Any and all actions taken by Amgen with respect to any of the matters alleged in the FAMCC were taken in good faith and in accordance with established industry practice.

#### **Tenth Defense**

Plaintiffs' and the putative class' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

# **Eleventh Defense**

Plaintiffs' and the putative class' claims are preempted by the dormant Commerce Clause of the United States Constitution.

# Twelfth Defense

Plaintiffs' and the putative class' claims against Amgen are barred because Amgen has complied with all applicable regulations of the federal and state governments.

## **Thirteenth Defense**

Plaintiffs' and the putative class' claims against Amgen are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

# Fourteenth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, because they violate Amgen's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, and the analogous provisions of the constitutions of the States whose laws are or become relevant during the course of this multidistrict litigation, insofar as Plaintiffs and the putative class members seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

# Fifteenth Defense

Amgen's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiffs or the putative class.

### Sixteenth Defense

Plaintiffs and the putative class fail to state with particularity facts to support the fraud allegations, and fail to plead with particularity the fraudulent concealment and multi-source medicine allegations against Amgen contained in the FAMCC.

#### **Seventeenth Defense**

Plaintiffs and the putative class fail to allege with particularity their civil conspiracy claims against Amgen as required by Fed. R. Civ. P. 9(b).

## **Eighteenth Defense**

Plaintiffs' and the putative class' claims against Amgen are barred, in whole or in part, because Amgen did not make any false statements to Plaintiffs or to any members of the putative class members. As to any statement asserted against Amgen that Plaintiffs and the putative class allege to be false or misleading, Amgen had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

#### **Nineteenth Defense**

Plaintiffs' and the putative class' claims against Amgen are barred because Amgen did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

#### **Twentieth Defense**

Plaintiffs' and the putative class' RICO claims against Amgen are barred, in whole or in part, due to Plaintiffs' failure to properly allege a RICO enterprise as required by 18 U.S.C. § 1962(c).

#### **Twenty-First Defense**

Plaintiffs' and the putative class' RICO claims against Amgen are barred, in whole or in part, due to their failure to plead facts showing that Amgen and the PBMs are ongoing organizations whose members function as continuing unit and share common purposes as required by *United States v. Turkette*, 452 U.S. 576, 583 (1981).

#### **Twenty-Second Defense**

Plaintiffs' and the putative class' RICO claims against Amgen are barred, in whole or in part, due to their failure to allege that Amgen conducted the affairs of the alleged enterprises as required by 18 U.S.C. § 1962(c).

#### **Twenty-Third Defense**

Plaintiffs and the putative class lack standing to bring their RICO claims against Amgen because they cannot show Amgen directly caused their alleged injuries as required by 18 U.S.C. § 1964(c); Holmes v. Securities Investor Prot. Corp., 503 U.S. 258, 265-66, 268 (1992); Platten v. HG Berm. Exempted Ltd., 437 F.3d 118, 132 (1st Cir. 2006); and George Lussier Enters. v. Subaru of New Eng., Inc., 393 F.3d 36, 51 (1st Cir. 2004).

# **Twenty-Fourth Defense**

Plaintiffs' and the putative class' civil conspiracy claims against Amgen are barred, in whole or in part, by their failure to allege a concerted action as required by *Aetna Cas*. *Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1564 (1<sup>st</sup> Cir. 1994) and *Grant v. John Hancock Mut. Life Ins. Co.*, 183 F. Supp. 2d 344, 359 (D. Mass. 2002), and/or by their failure to allege a coercive conspiracy as required by *Fleming v. Dance*, 22 N.E.2d 609, 611 (Mass. 1939).

# **Twenty-Fifth Defense**

Plaintiffs' and the putative class' civil conspiracy claims against Amgen are barred, in whole or in part, because they are duplicative and improper under Massachusetts law. *See Grant*, 183 F. Supp. 2d at 364.

# **Twenty-Sixth Defense**

Amgen denies that Plaintiffs and the putative class have valid consumer protection claims against Amgen under any of the State consumer protection laws alleged in this Complaint or any other State whose law is or becomes relevant in the course of this multidistrict litigation. However, if such claims are found to exist, Amgen pleads all available defenses under the Acts.

#### **Twenty-Seventh Defense**

Any allegedly fraudulent statements or conduct of Amgen did not directly or proximately cause the alleged injuries of Plaintiffs and/or any members of the putative class as required under state consumer protection laws, including without limitation any of the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation.

#### Twenty-Eighth Defense

Amgen's conduct was not "knowing," "deceptive," "misleading," "unlawful," a "misrepresentation" or "illegal" as required under certain state consumer protection laws, including without limitation to any of the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation.

#### **Twenty-Ninth Defense**

To the extent that Plaintiffs and the putative class members attempt to seek equitable relief against Amgen, they are not entitled to such relief because they have an adequate remedy at law.

#### Thirtieth Defense

Plaintiffs and the putative class lack either standing or capacity, or both, to bring some or all of the claims alleged against Amgen in the Complaint.

#### **Thirty-First Defense**

Plaintiffs and the putative class did not rely on the allegedly fraudulent statements or conduct of Amgen as required under certain state consumer protection laws, including without limitation any of the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation.

# **Thirty-Second Defense**

Any allegedly fraudulent statement or conduct of Amgen was not consumeroriented as required under certain consumer protection law, including without limitation any of the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation.

#### **Thirty-Third Defense**

To the extent the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation do not recognize a private right of action, Plaintiffs are not entitled to relief under the applicable statutes.

# **Thirty-Fourth Defense**

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation bar class actions, Plaintiffs are not entitled to relief under the applicable statutes.

#### **Thirty-Fifth Defense**

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation limit claims to those brought by "consumers," Plaintiffs are not entitled to relief under the applicable statutes.

#### **Thirty-Sixth Defense**

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation require Plaintiffs to send a written demand for relief to Defendants prior to filing a Complaint, Plaintiffs have failed to do so and are not entitled to relief under the applicable statutes.

#### **Thirty-Seventh Defense**

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation require Plaintiffs to attempt Alternative Dispute Resolution prior to filing a Complaint, Plaintiffs have failed to do so and are not entitled to relief under the applicable statutes.

#### **Thirty-Eighth Defense**

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict

litigation require Plaintiffs provide notice of the practice at issue to the relevant State Attorney General, Plaintiffs have failed to do so and are not entitled to relief under the applicable statutes.

#### **Thirty-Ninth Defense**

To the extent that the State consumer protection laws alleged in this Complaint or those of any other State whose laws are or become relevant in the course of this multidistrict litigation limit Plaintiffs' available remedies, Plaintiffs are not entitled to their requested relief under the applicable statutes.

#### Fortieth Defense

Plaintiffs' and the putative class' claims against Amgen for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

# **Forty-First Defense**

Plaintiffs' and the putative class' claims for injunctive relief against Amgen are barred by the doctrines of *in pari* delicto and/or unclean hands.

#### **Forty-Second Defense**

This action cannot be maintained as a class action because (1) the certification and maintenance of this action as a class would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch; (2) the claims of Plaintiffs and the putative class cannot be properly joined with one another because they did not arise out of the same transaction, occurrence, or series of transactions or occurrences; (3) the named Plaintiffs and the putative class cannot satisfy the procedural requirements of Fed. R. Civ. P. 23; (4) the questions of fact at issue are not common to the alleged class, but rather, are highly specific and will vary dramatically from person to person and entity to entity; and/or (5) class certification would violate Amgen' rights provided

by the Fifth, Seventh and Fourteenth Amendments to the United States Constitution as well as by the Constitutions of any State whose consumer protection laws are specified in this Complaint and any other States whose laws are or become relevant in the course of this multidistrict litigation, including but not limited to Amgen' right to procedural and substantive safeguards, which include traditional defenses to liability.

# **Forty-Third Defense**

Plaintiffs' and the putative class' claims against Amgen under the various state consumer protection and consumer fraud statutes are barred, in whole or in part, to the extent those statutes (1) do not allow (or did not allow at the time the conduct was alleged herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly interstate in nature.

# Forty-Fourth Defense

Plaintiffs' and the putative class' claims against Amgen under the various state unfair trade, unfair competition, consumer protection and consumer fraud statutes are barred to the extent (1) those claims represent an impermissible circumvention of the states' antitrust statutes; and (2) those statutes apply only to deceptive or misleading conduct and/or govern only consumer transactions.

#### **Forty-Fifth Defense**

Third party payor Plaintiffs' and third party payor putative class members' claims against Amgen are barred, in whole or part, with respect to any alleged overcharge or supracompetitive price on the ground that third party payors passed on any effect of the alleged supracompetitive prices to their customers or employees in the form of higher premiums, co-pays or other charges.

# Forty-Sixth Defense

Plaintiffs' and the putative class' claims against Amgen are barred, in whole or in part, with respect to any alleged overcharge or supra-competitive price because such supra-competitive price, if any, was absorbed, in whole or part, by a person and/or entity which purchased the medicine directly, and/or by an intermediate indirect purchaser, and was not passed through to the Plaintiffs and putative class members.

#### **Forty-Seventh Defense**

Plaintiffs' and the putative class' claims against Amgen are barred, in whole or in part, due to their failure to join indispensable parties.

# Forty-Eighth Defense

Plaintiffs' and the putative class' claims against Amgen are barred, in whole or in part, because they have suffered no damages as a result of the matters alleged in the FAMCC.

#### **Forty-Ninth Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, because any injuries sustained by Plaintiffs or the putative class were the result of intervening or superseding conduct of third parties.

#### Fiftieth Defense

Plaintiffs' and the putative class' claims against Amgen for damages are barred, in whole or in part, (1) because they failed to mitigate their damages, and their failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Amgen; (2) because they would be unjustly enriched if allowed to recover any portion of the damages alleged in the FAMCC; (3) by the doctrine of consent and/or ratification to the extent that Plaintiffs and/or putative class members have received and

paid for medicines manufactured, marketed and sold by Amgen after the filing of Plaintiffs' original Complaint; and (4) because they are speculative and remote and because of the impossibility of ascertaining and allocating of those alleged damages.

#### <u>Fifty-First Defense</u>

Amgen is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs and/or the putative class, with respect to the same alleged injuries.

## Fifty-Second Defense

Any damages recovered by the Plaintiffs and the putative class from Amgen must be limited by the applicable statutory ceilings on recoverable damages.

#### **Fifty-Third Defense**

Plaintiffs and the putative class fail to allege facts or a cause of action against Amgen sufficient to support a claim for attorneys' fees, treble damages and/or legal fees.

#### Fifty-Fourth Defense

To the extent punitive damages are sought, Plaintiffs' and the putative class' punitive damages claims against Amgen: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the FAMCC are legally insufficient to support a claim for punitive damages against Amgen; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give Amgen prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of Amgen' due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitutions and the constitutions of any applicable states' laws; (4) cannot be sustained because any award of punitive damages

exceeding the limits authorized by the laws or other comparable laws would violate Amgen' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and applicable states' laws; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, of subsequent judgments against Amgen for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Amgen' medicines would constitute impermissible multiple punishments for the same wrong, in violation of Amgen' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the constitutions, common law and statutory law of any applicable states' laws; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Amgen' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' law; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according Amgen the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Amgen' rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the constitutions, common law and public policies of any applicable states' laws.

#### Fifty-Fifth Defense

To the extent punitive damages are sought, Plaintiffs' and the putative class' claim for punitive damages against Amgen cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award, (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment, (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Amgen, (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible, (5) is not properly instructed regarding Plaintiff's and the putative class' burden of proof with respect to each and every element of a claim for punitive damages, or (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Amgen' Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the constitutions, common law and public policies of any applicable states' laws.

#### Fifty-Sixth Defense

To the extent punitive damages are sought, Plaintiff's and the putative class' claim for punitive damages against Amgen cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as maximum multiple of compensatory

damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Amgen' due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Amgen' right not to be subjected to an excessive award; and (3) be improper under the constitutions, common law and public policies of any applicable states' laws.

#### Fifty-Seventh Defense

Plaintiffs' and the putative class members' claims are barred, in whole or in part, because they conflict with federal statutes and regulations that comprise a comprehensive regulatory regime governing the amounts paid to providers for Medicare Part B covered drugs.

# Fifty-Eighth Defense

Plaintiffs and the putative class members are not entitled to relief requested in the Complaint because the Court lacks any sufficiently certain, nonspeculative basis for fashioning such relief.

#### Fifty-Ninth Defense

Plaintiffs and the putative class members are barred from recovery because the representations and actions alleged by Plaintiffs were not and are not material, in that they were not and are not likely to affect the decisions or conduct of Plaintiffs and putative class members, or to have caused consumers or Third-Party Payors to have chosen differently, but for such alleged representations or actions, in light of the information available and known to consumers and Third Party Payors, and in that the alleged representations and actions were not likely to mislead consumers or Third Party Payors acting reasonably under the circumstances.

# Sixtieth Defense

Plaintiffs' and the putative class members' claims against Amgen under the various state unfair and deceptive trade practice or consumer protection or consumer fraud statutes are barred, in whole or in part, because excess-provider-profit claims are inherently speculative and subjective and not subject to judicial resolution.

# **Sixty-First Defense**

Plaintiffs' and the putative class members' claims fail, in whole or in part, because of improper claim splitting.

## **Sixty-Second Defense**

Plaintiffs' and the putative class members' antitrust claims against Amgen are barred in whole or in part because; (1) they have not suffered any antitrust injury; (2) they lack standing; and/or (3) the alleged conspiracy does not make economic sense and is economically implausible.

#### **Sixty-Third Defense**

Any alleged restraints complained of in the FAMCC are ancillary to legitimate, pro-competitive activity.

#### Sixty-Fourth Defense

Plaintiffs and putative class members are precluded from recovery because the representations and actions alleged by Plaintiffs were not included to deceive Plaintiffs and the putative class members.

# Sixty-Fifth Defense

Amgen is not liable to Plaintiffs and the putative class members because it had no duty to disclose the information allegedly not disclosed.

#### Sixty-Sixth Defense

Plaintiffs' and the putative class members' claims against Amgen under Section 1 of the Sherman Act, 15 U.S.C. § 1, are barred to the extent recovery is based on indirect purchases of medicines.

# Sixty-Seventh Defense

Plaintiffs' and the putative class members' claims against Amgen are barred, in whole or in part, by the doctrines of assumption of risk and/or comparative fault or negligence.

#### Sixty-Eighth Defense

Plaintiffs' and the putative class members' claims for equitable relief are barred because equitable relief is not available under any of the alleged causes of actions.

# **Sixty-Ninth Defense**

Amgen adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

#### Seventh Defense

Amgen hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its answer to assert such defense. Amgen also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part thereof, is governed by the substantive law of a state other than any State whose consumer protection laws are specified in this Complaint and/or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

WHEREFORE, Amgen prays that this Court:

1. Dismiss the Fourth Amended Master Consolidated Class Action

Complaint with prejudice and enter judgment in favor of Amgen and against Plaintiffs;

- 2. Award Amgen its costs and expenses; and
- 3. Grant such other and further relief for Amgen as this Court deems just and

Respectfully Submitted,

Dated: May 15, 2006

proper.

/s/ Douglas S. Brooks

Frank A. Libby, Jr. (BBO No. 299110) Douglas S. Brooks (BBO No. 636697) Kelly, Libby & Hoopes, P.C. 175 Federal Street, 8<sup>th</sup> Floor Boston, Massachusetts 02110 Telephone: (617) 338-9300

Facsimile: (617) 338-9911

Joseph H. Young Steven F. Barley Jennifer A. Walker Hogan & Hartson L.L.P. 111 S. Calvert St., Suite 1600 Baltimore, Maryland 21202 Telephone: (410) 659-2700

Facsimile: (410) 539-6981

Counsel for Amgen Inc.

# **CERTIFICATE OF SERVICE**

I hereby certify that on this 15th day of May 2006, a true and correct copy of AMGEN INC.'S ANSWER TO PLAINTIFFS' FOURTH AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT was served upon all counsel of record via electronic service pursuant to CMO No. 2 by causing a copy to be sent to LexisNexis File & Serve for posting and notification.

/s/ Jennifer A. Walker
Jennifer A. Walker